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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,976	02/13/2004	Naoko Tsuji	248798US CONT	7448
22850	7590	09/25/2006	EXAMINER	
C. IRVIN MCCLELLAND OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			FLOOD, MICHELE C	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/777,976

Applicant(s)

TSUJI ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-10 is/are pending in the application.
- 4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/614,166.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 7-9; and the species in Claim 7 of a rye malt and the species in Claim 8 of the solvent which includes mixtures of water and alcohol, in the reply filed on August 15, 2006 is acknowledged. The traversal is on the grounds that no adequate reasons and/or examples have been provided or shown that a burden on the Examiner to search both inventions given the limited number of ingredients involved in each group. This is not found persuasive for reasons set forth clearly in the previous Office action. In the instant case, the two different groups are directed to two different methods of inhibiting hair growth comprising the administration of different ingredients. These methods are capable of separate manufacture, use or sale, as claimed, and are patentable (novel and unobvious) over each other (though they may be unpatentable because of the prior art) subjects. One would not have to practice the various methods at the same time to practice just one method alone.

The inventions above are independent and distinct, each from the other. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

The requirement is still deemed proper and is therefore made FINAL.

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Claims 7-9 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting hair growth comprising administering to a surface of skin in need thereof an effective amount of ethanolic extracts of the stems and leaves of *Juniperus virginiana* L., *Juniperus morrisonicola* Hayata, *Juniperus formosana* Hayata, and the raw grain of *Triticum aestivum* L., does not reasonably provide enablement for a method of hair growth inhibition comprising the administration to a surface of skin in need thereof any and all solvent extracts of *Juniperus* plant extracts or any all solvent extracts of a rye malt or an oat malt. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as broadly claimed.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (A)).

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill in the art; (f) the amount of direction provided by the

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inventor; (g) the existence of working examples; and (h) the quantity of experimentation added to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The claims are drawn to a method of inhibiting hair growth comprising administering to a surface of skin in need thereof an effective amount of a plant extract selected from the group consisting of *Juniperus* plant extracts, rye malt, oat malt and mixtures thereof. The claims are further drawn to wherein the plant extract is an extract of a solvent selected from the group consisting of water, an alcohol and mixtures thereof; and wherein the plant extract is present in an amount of 0.00001 to 50 weight (wt.) %.

The specification is non-enabling for the claim designated method as the specification does not provide guidance as to how to identify any and all solvent extracts of each of the members comprising *Juniperus* plant extracts, rye malt, oat malt and mixtures thereof; how to determine the solvents used in the making of any and all of the claim designated plant extracts; how to determine which parts of the plants to use in the making of the claim designated plant extracts; and how to determine the effective therapeutic amounts of any and all of the claim designated plant extracts such that the plant extract is effective in inhibiting hair growth.

The specification broadly discloses a method for the administration of plant extracts of the genus *Juniperus* or a malt extract, such as a rye malt or an oat malt for the inhibition of hair growth. While the specification does demonstrate a method for the

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inhibition of hair growth comprising the administration to the surface of a skin an ethanolic extract of leaves and stems of *Juniperus virginiana* L., *Juniperus communis*, and the raw malt of *Triticum aestivum* L., wherein the administration appears to be effective in the inhibition of the regrowth of hair, the specification does not disclose a method for the inhibition of hair growth comprising the administration of any and all members of the genus *Juniperus* plant extracts, rye malt, oat malt and mixtures thereof. However, nowhere in the specification does Applicant disclose a method of inhibiting hair growth comprising the administration of a rye malt or an oat malt or mixtures thereof or mixtures thereof further comprising a *Juniperus* plant extract(s). While the specification envisions a method of inhibiting hair growth comprising administering to a surface of skin in need thereof an effective amount of a plant extract selected from the group consisting of a *Juniperus* plant extract, rye malt, or oat malt and mixtures thereof, no working examples or data therefrom are provided that demonstrate that the administration of effective amounts of the claim-designated composition of a rye malt malt or an oat malt or mixtures thereof or mixtures thereof further comprising a *Juniperus* plant extract(s) have the beneficial functional effect of inhibiting hair growth when administered to a surface of skin in need thereof.

The state of the art at the time of filing suggests that the administration of the claim designated *Juniperus* plant extract within the range of the claim designated therapeutic amounts have not been established to have the atypical functional effect as disclosed by Applicant. For instance, Betourne (AS, FR 2709952 A1) teaches that the administration of *Juniperus* has the functional effect for the promotion of hair growth.

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Moreover, Rahmatollah (N, FR 2558727 A1) teaches a method of administering a composition comprising an aqueous extract of *Juniperus* to a surface of a skin (for example, the scalp) for the reduction of hair loss.

The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not relay on the prior art or instant specification to teach how make and/or use the instantly claimed method for the inhibition of hair growth comprising administering any and all amounts or any and all solvent extracts or any and all solvent extracts comprising any and all plant parts wherein the plant extract is selected from the group consisting of a *Juniperus* plant extract, rye malt, or oat malt and mixtures thereof, no working examples or data therefrom are provided that demonstrate that the administration of effective amounts of the claim-designated composition of a rye malt malt or an oat malt or mixtures thereof or mixtures thereof further comprising a *Juniperus* plant extract(s) have the beneficial functional effect of inhibiting hair growth when administered to a surface of skin in need thereof,

In order to carry out the claimed invention, one of skill in the art would have to identify what type of each of the claim designated plant extracts or mixtures thereof, the amount of each of the plant extract or mixtures thereof to be included in the claim-designated composition, and the type of solvent and/or plant parts would be useful in the making of a composition that would be useful in the making of a composition that would be useful to provide a method of inhibiting hair growth comprising the claim designated ingredients and claim designated experimental parameters. There is no guidance in the specification, other than the ethanolic extracts using the leaves of

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Juniperus virginiana and *Juniperus communis*, and an ethanolic malt extract of *Triticum aestivum* L. Thus, Applicant has not demonstrated that the claimed functional effect of inhibiting hair growth comprising the administration of any and all plants of the genus *Juniperus*, much less the claimed functional effect of inhibiting hair growth comprising administering a rye malt or an oat malt, or mixtures thereof. Accordingly, it would take undue experimentation without a reasonable expectation of success how to determine which plant members of the genus *Juniperus*, any and all members of the claim designated malt group of rye and oat and mixtures thereof; how to determine the solvents used in the making of any and all of the claim designated plant extracts or mixtures thereof; and how to determine the plant parts used in the making of the claim designated plant extracts or mixtures thereof; and how to determine the therapeutic amounts of any all of the claim designated plant extracts such the plant extract is effective in inhibiting hair growth.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, it would take undue experimentation without a reasonable expectation of success for the skilled artisan to make and/or use the instantly claimed method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-9 are rendered vague and indefinite by the term "extract" because this term, in and of itself, does not adequately delineate its metes and bounds. This term is best defined as a product-by-process since product-by-process claims are intended to define products which are otherwise difficult to define (and/or distinguish from the prior art). For example, is the extract obtained via extraction with water, a polar solvent, a non-polar solvent, an acid or base, a squeezed extract, or something else? In addition, from what part(s) of the plant is the extract obtained? It is well accepted in the herbal art that extraction with one of various distinct solvents, as well as from particular parts of therapeutic plants, has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein and, thus, its ability to provide the desired functional effect(s) instantly claimed and/or disclosed. Since the extract itself is clearly essential to the claimed invention, the step(s) by which the claimed extract is obtained are also clearly essential and, therefore, must be recited in the claim language itself (i.e., as a product-by-process). Please note that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

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Abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter. Claim 9, line 2, recites the abbreviation "wt%". Applicant can overcome the rejection by replacing "wt%" with weight (wt.) % or weight.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 5 of U. S. Patent No. 6,375,948 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 7-9 are generic to all that is recited in claims 1 and 5 of U. S. Patent No. 6,375,948 B1. That is, Claims 7-9 fall entirely within the

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scope of claims 1 and 5 of U. S. Patent No. 6,375,948 B1, or in other words, Claims 7-9 are anticipated by claims 1 and 5 of U. S. Patent No. 6,375,948 B1 because the actual process steps, process materials, process parameters, and resulting functional effect of the process are the same.

Thus, Claims 7-9 are no more than obvious variants of the limitations of the patented subject matter of U. S. Patent No. 6,375,948 B1.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
September 18, 2006


MICHELE FLOOD
PRIMARY EXAMINER